HILLCREST MEDICAL CENTER UTICA ON THE PARK, TULSA, OKLAHOMA 74104 TELEPHONE: 918 584-1351

August 15, 1985

Jack Whitten
U.S. Nuclear Regulatory Commission, Region IV
Material Radiation Protection Section
611 Ryan Plaza Dr., Suite 1000
Arlington, TX 76011

Dear Mr. Whitten:

Please accept this letter as our formal request to amend our present institutional license (#35-09206-03). We propose to use Gadolinium-153 in the form of a sealed source for the purpose of measuring and evaluating bone mineralization content. Specific information relating to the safe use and disposal of the radioactive materials is enclosed to support the license amendment request.

The radioactive source material, Gadolinium-153 (Gd-153) will be used in a chemical state of GdO_2 and purchased from the Radiation Sources Department of Amersham Corporation (see Attachment A).

Although we plan to use no more than 1300 millicuries of Gd-153 source material in the bone mineral analyzer, we would like to request authorization for a maximum possession at any one time of 2400 millicuries. This would allow continuity of patient scanning in the event unplanned circumstances prevented the use of the original source material. This incident would obviously require the return of the source to the manufacturer. Secondly, this maximum limit possession amount (2400 millicuries) would be more than adequate to include summed activities of a spent source in addition to the newly acquired replacement.

The Gd-153 sealed source will be used in a "Lunar Radiation Corporation Model DP3 Bone Mineral Analyzer" (reference by NRC registration number GDC-C41, see Attachment B). The manufacturer's procedure for loading and unloading of the Gd-153 radioactive sealed source will be stringently followed. A copy of this procedure is enclosed as attachment for your review. Procedures included in our renewal application dated 2-1-84 and on file at the NRC regional office will provide approved methodologies used in assuring safe and acceptable practices regarding "Procedures for Ordering and Receiving Radioactive Materials", "Procedures for Safely Opening Packages Containing Radioactive Materials", "Area Survey Procedures", "Emergency

Procedures" and other applicable regulations.

The spent Gd-153 sealed source will be forwarded to the manufacturer (Amersham Corporation) for proper disposal. The manufacturer will be notified prior to the shipment and will be informed as to the specific details of such action. Should the manufacturer refuse delivery for any reason, the Nuclear Regulatory Commission will be notified promptly and an alternate site will be sought.

The space formerly labeled the uptake room as listed in Attachment 4 of NRC 313M renewal application dated 2-1-84, will be used for the bone mineral analyzer. Room configurations illustrated in attachments D and E of this correspondence. The uptake equipment will be moved into scan room III where the mobile scintillation camera presently resides. Both the mobile camera and uptake system will be positioned in the room (see Attachment F) and will be used independent of the other. At no times will we perform concurrent examinations on the equipment. Except during source exchanges, the Gd-153 source will be contained within the Lunar DP3 analyzer. The source will be confined in a lead lined source holder, Lunar Model A-SRC-0100-0. During the exchange process, the source will be temporarily stored in the Hot Lab and appropriately secured.

In accordance with Part 20.203 of CFR Title 10, Chapter 1 NRC Rules and Regulations, the room designated as scan room IV will be properly labeled with approved "Caution - Radioactive Materials" sign. Further, scan room IV is located in an area defined as restricted or unauthorized and is included within the Nuclear Medicine Department (see Attachment D). The Department of Nuclear Medicine is appropriately locked during nonbusiness hours to prevent unauthorized entry.

Pursuant to Part 170 of CFR Title 10, Chapter 1 NRC Rules and Regulations, please find enclosed a check for $120.00 made payable to the NRC for the purpose or processing this amendment request.

Finally, we request that Myron R. Goede, M.S., Radiation Safety Officer be removed from our institutional license and replaced by Michael Sanders, PHD. Dr. Sanders' qualification as a Radiation Safety Officer is illustrated in Attachments G and H. Dr. Sanders has accepted full time employment at Hillcrest Medical Center effective 6-17-85 and will function in the capacity of a health physicist in Radiation Therapy and Radiation Safety Officer for the institutional license.

As Dale Harris mentioned to you during our recent telephone conversation, we would certainly appreciate it if prompt action could be taken on this request. Our medical staff is eager to add this particular modality to the wide range of diagnostic services available to them. Therefore, to expedite this process, you may want to interact with Mr. Harris directly if such action is necessary. He may be reached by calling (918) 584-1351 x 1053. Thank you in advance for review of this application and if you need additional information or simply clarification of submitted materials, please do not hesitate to contact us.

Respectively submitted,

Steven Landgarten, M.D.
Vice President, Medical Affairs

Amersham MARKETING COMMUNICATIONS

GADOLINIUM-153 SOURCES
FOR BONE MINERAL ANALYSIS AND RESEARCH STUDIES
AMERSHAM PRODUCT CODE GDC.10413

Amersham Corporation is pleased to announce its intention to supply high activity Gadolinium-153 sources to service the needs of workers in bone mineral analysis and related nuclear medicine fields. These sources will compliment Amersham Corporation's existing range of sources for bone mineral analysis. The use of these radiation source/holder assemblies when used as a component in a Lunar Radiation DP-3 or DP-4 dual photon absorptiometer allows for sensitive measurement of bone mineral content to aid in the diagnosis and monitoring of bone disease.

The illustration overleaf shows Amersham's 7mm diameter x 10mm long X1041 capsule mounted into a Lunar Radiation supplied Gadolinium-153 source holder. This assembly (Amersham product code GDC.10413) is designed for compatibility with either the Lunar Radiation DP-3 Spine/Femur scanner or DP-4 Total Body scanner.

Amersham Features

- Safety

  Each source contains the radionuclide in a 3mm diameter pressed pellet form which is recessed into a stainless steel insert and sealed into a TIG welded titanium capsule. Each capsule supplied with Amersham leak and wipe test certificate.

- Regulatory Approval

  The Amersham Gadolinium-153 source in X1041 capsule has been listed as suitable for licensing by the USNRC under model no. GDC.CY1.

- High Integrity Capsules

  Only the highest quality titanium is used to maintain the highest integrity capsules available. Each capsule meets the safety performance testing of ANSI/ISO 77C64444. This rating means that the Amersham capsule is the strongest available yet highest output.

- High Output

  Each source is guaranteed to meet a minimum photon output of 1.0×10^9 photon/sec per steradian for the Eu K X-rays. The use of our titanium capsule facilitates higher 41-48 keV X-rays emission than stainless steel capsules or thick windowed aluminum capsules. This is because of the strong but thin (0.2mm) windows made possible by using titanium.

- Spectral Purity

  High radionuclidic purity of >99.99% is specified for the Gadolinium-153 and maintained due to Amersham's dedicated facility in which only Gadolinium-153 sources are manufactured.

- International Shipping

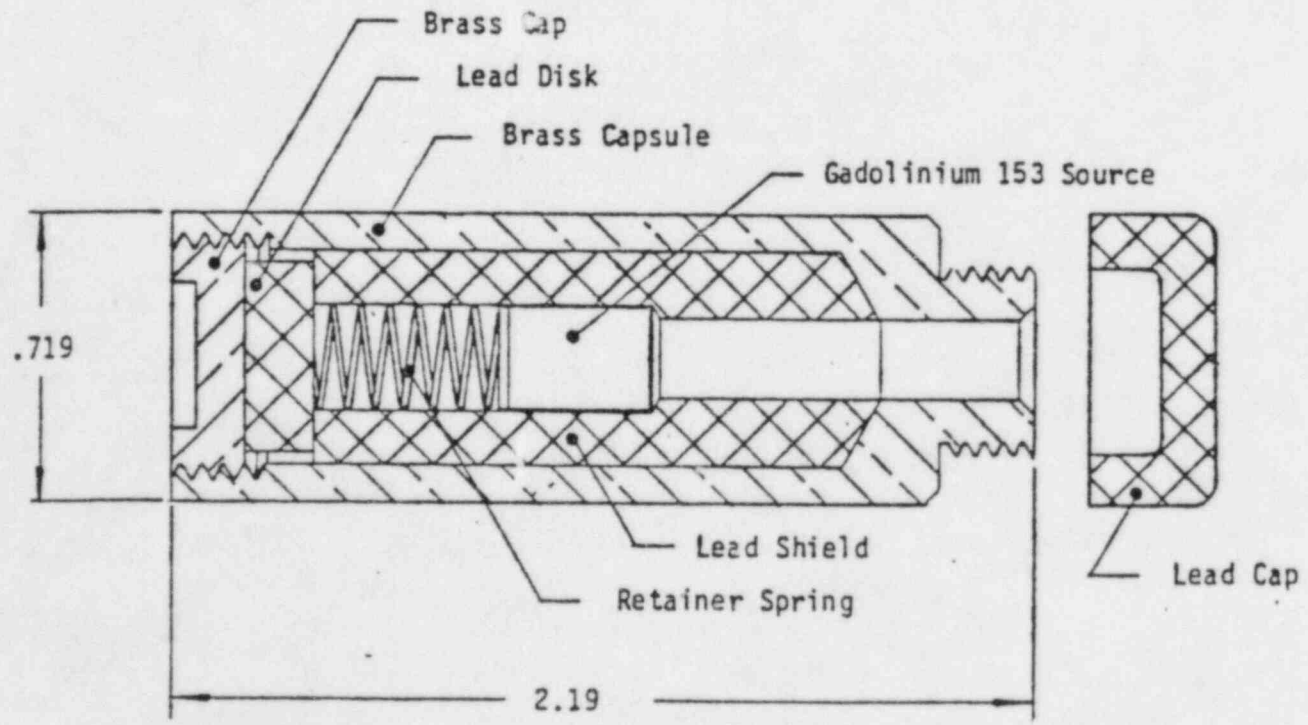
  Amersham's worldwide distribution network and expertise along with the necessary containers all aid in direct shipments to most locations..

- Measurement Assurance

  Amersham participates in intercomparison programs with NBS and other national laboratories to assure output measurement accuracy.

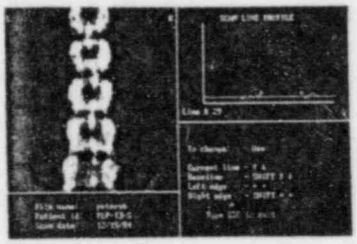
For a full updating of our source program, please contact Amersham customer service at 1-800/323-6695. For written orders or inquiries, please send to:

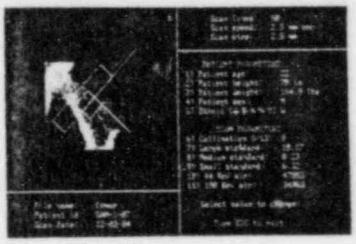
Amersham Corporation
Radiation Sources Department
2636 S. Clearbrook Drive
Arlington Heights, IL 60005



Attachment B

LUNAR DP3-XT/AT, The Unique Clinical Solution For Bone Densitometry





Over a decade of research and clinical testing has gone into the LUNAR DP3 dual-photon spine/femur scanners. LUNAR scientists pioneered both single and dual-photon absorptiometry and helped LUNAR become the world's largest manufacturer of bone measurement instrumentation.

LUNAR now offers the IBM-XT and AT as options to our acclaimed DP3 scanner. Advanced features of the DP3-XT/AT include:

–Multi-tasking
–Automated peaking
–High-resolution color graphics
–Hard-disk storage

LUNAR continues to set the standard for bone measurement. These new features, plus a light-localizer and a belly-band, add to the DP3's proven capability.

Contact us to see why the clinical leaders have turned to LUNAR with confidence.

Ask A User!

Our customers comprise over 85% of all clinical facilities using dual-photon absorptiometry. They selected the DP3 because LUNAR's exclusive know-how ensures trouble-free, question-free operation and because of distinct advantages such as:

–**Intelligent scans** that reduce scan area, scan time, and patient exposure.
–**Multiple sites**—lumbar spine, proximal femur, tibia, proximal humerus and other areas
–**Graphics displays**—ultrafast, high-resolution images
–**Normal database** of US subjects
–**Accuracy/precision** based on physically correct algorithms
–**High patient throughput** with 15-minute scans
–**Sophisticated software** that takes the guesswork out of scanning
–**Medical physics support** from our in-house staff
–**Software updates**—free-of-charge
–**Service**—1-year warranty with 24-hour response
–**Lower cost**—extended source life
–**Operational ease**—menu-driven, automated software

LUNAR RADIATION CORPORATION

916 Williamson Street
Madison, Wisconsin 53703
(608) 258-8545

C.2 INSTALLING AND REMOVING THE SOURCE

WARNING: Only personnel trained in the principles of radiation safety and protection should conduct these procedures. The technician should study the following procedures before an actual source transfer is attempted. The press-on lablel withe the warning "CAUTION - RADIOACTIVE MATERIALS" should be affixed to the table of the scanner in a location where it can be seen by the operator, patients and/or visitors to the area where measurements are done.

All steps can be conducted without tools. Use of pliers, clamps, etc. in the procedures may cause damage to parts. The "source" consists of a capsule containing gadolinium in solid form (FIG 9). This source is encapsulated in a lead-lined (4mm) brass source holder (FIG 10).

C.2.a. Removing the Source

PROCEDURE

1. Remove pad (if any) and the lucite insert from the table.

2. Use OPTION 5 (Static Counter, User Manual) of the CLUNAR program to position the arm and source at the center of the window.

3. Place a lead source holder cap onto the source collimator (FIG 11).

4. Use the "shutter open" command of OPTION 5. Alternatively the shutter can be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the shutter is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this (open) position.

5. Turn the chuck ring (FIG 12) counterclockwise until the collimator is loose in the chuck. Do not completely loosen the chuck ring.

6. Pull the source collimator (which will have the source holder attached to the end of it) out of the chuck. The source collimator and holder can now be handled as a unit.

8. Holding the source collimator and souce-holder upright (as they were positioned in the scanner), unscrew the source-holder from the collimator. Put a lead cap on the source holder.

   CAUTION: RADIATION PRESENT! After the collimator is removed a broad beam of high intensity radiation projects from the top of the source-holder. Exercise due caution.

FIGURE 10
Source Holder for 153-Gd Capsule

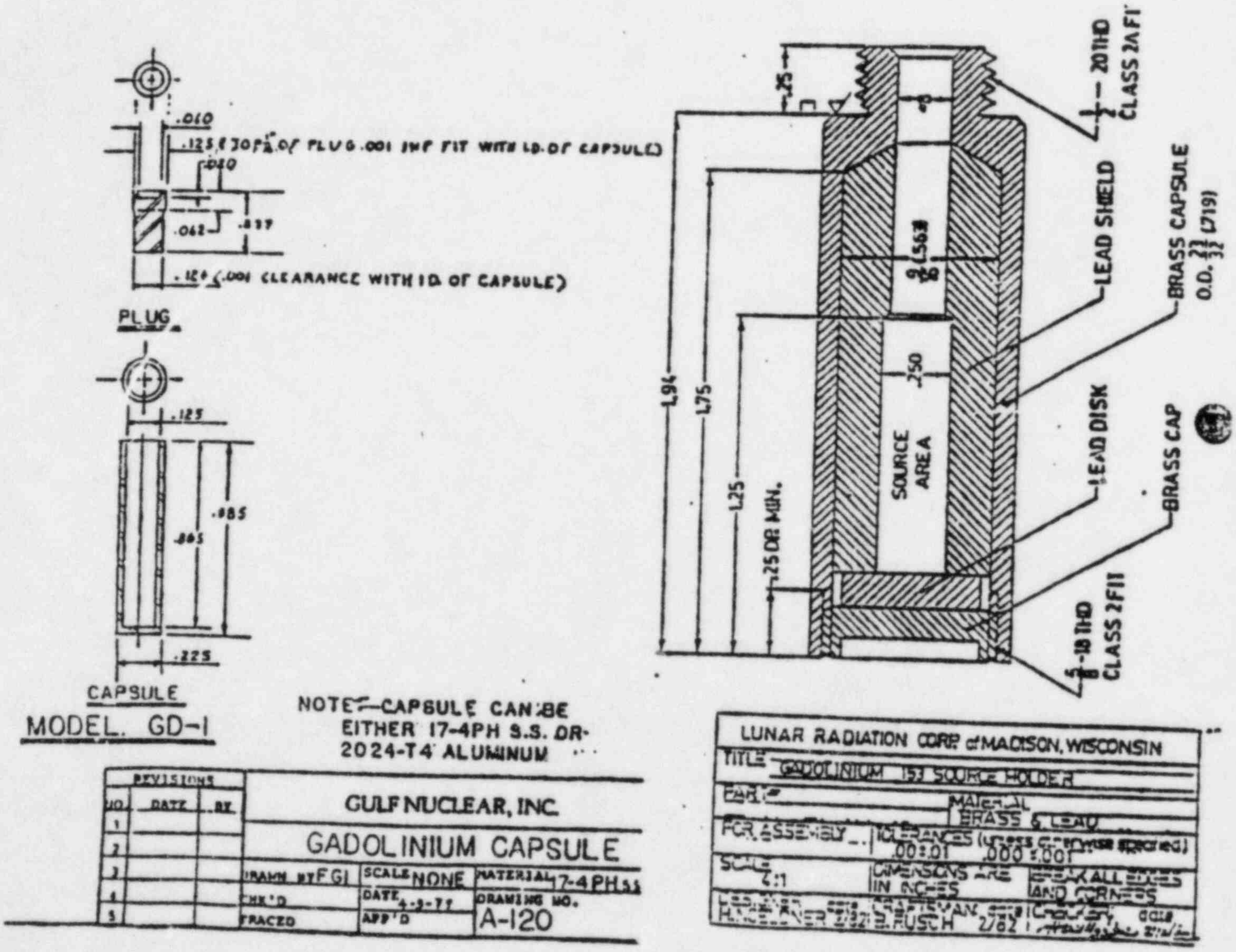


FIGURE 11
Source Collimator/Holder Assembly

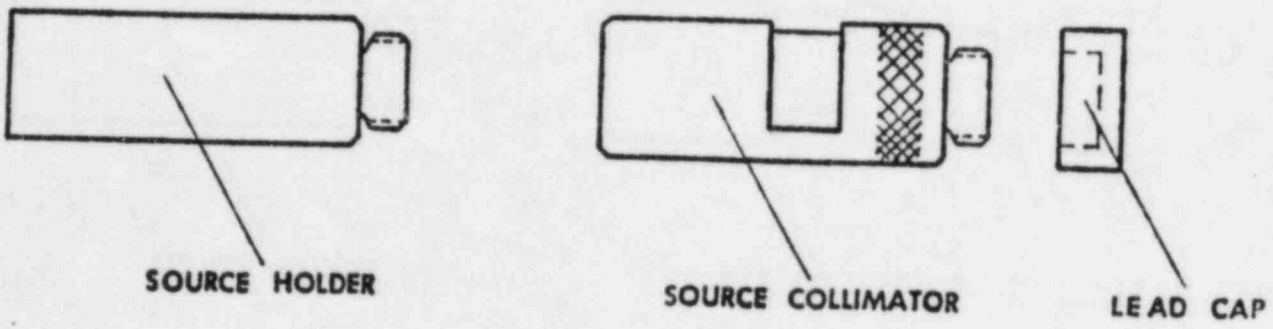


FIGURE 12
Side View of Transverse Carriage

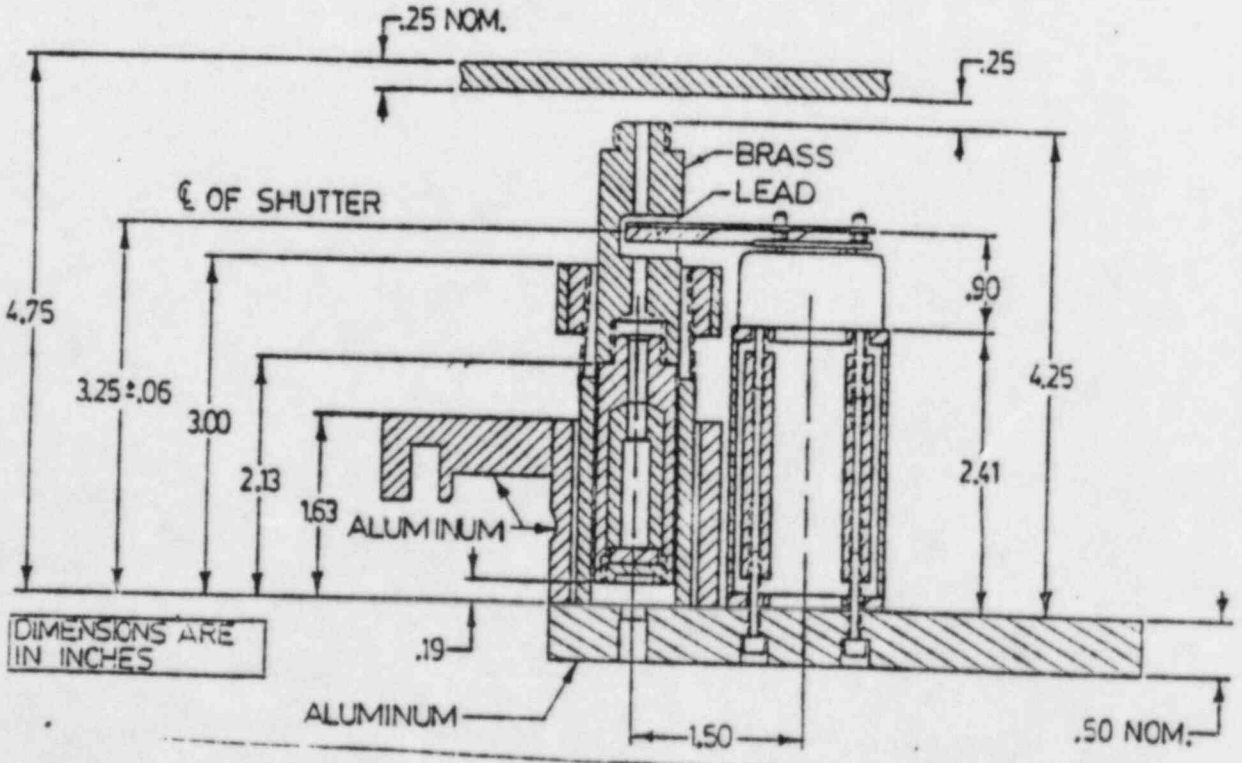
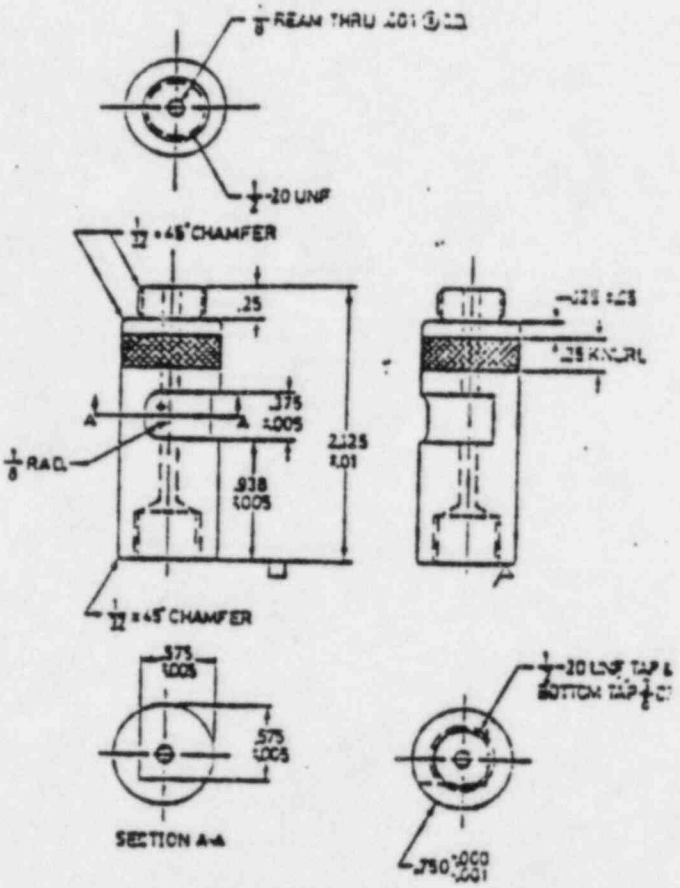


FIGURE 13
Collimator Details



LUNAR RADIATION CORP. MADISON, WISCONSIN	
TITLE DP3 SOURCE COLLIMATOR (REVISED)	
PART #	MATERIAL BRASS
FOR ASSEMBLY	TOLERANCES UNLESS OTHERWISE STATED .00 ±.01 .000 ±.001
SCALE NONE	DIMENSIONS ARE IN INCHES
DRAWN H.NCE/DNER 2-27-78	CHECKED RUSCH 2/78

C.2.b Installing a Source

1. Use the "shutter open" command of OPTION 5. Alternatively the shutter can be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the shutter is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this (open) position.

2. For new scanners the source holder is provided with the source. The collimator will not have a cap. Remove the collimator from the scanner.

3. Place the lead cap on the source holder onto the brass collimator provided with the scanner. Thread the source holder onto the base of the collimator. Do not force the collimator onto the source holder or it may cross-thread. The source collimator and holder can now be handled as a unit.

4. Slide the source collimator-holder into the source chuck (Fig. 12) so that the pin on the bottom fits into the notch on the source chuck. The collimator shoulder should rest on the top of the chuck (not the chuck ring).

5. Use the "shutter close" command of OPTION 5 or remove the tape if the shutter is held open manually.

6. Verify that the shutter can swing into the notch on the collimator (Fig. 12).

7. Turn the chuck ring clockwise until the collimator is held firmly in the chuck.

8. Remove the source holder cap from the top of the collimator.

   CAUTION: A narrow beam of intense radiation is now projected upward from the collimator aperture.

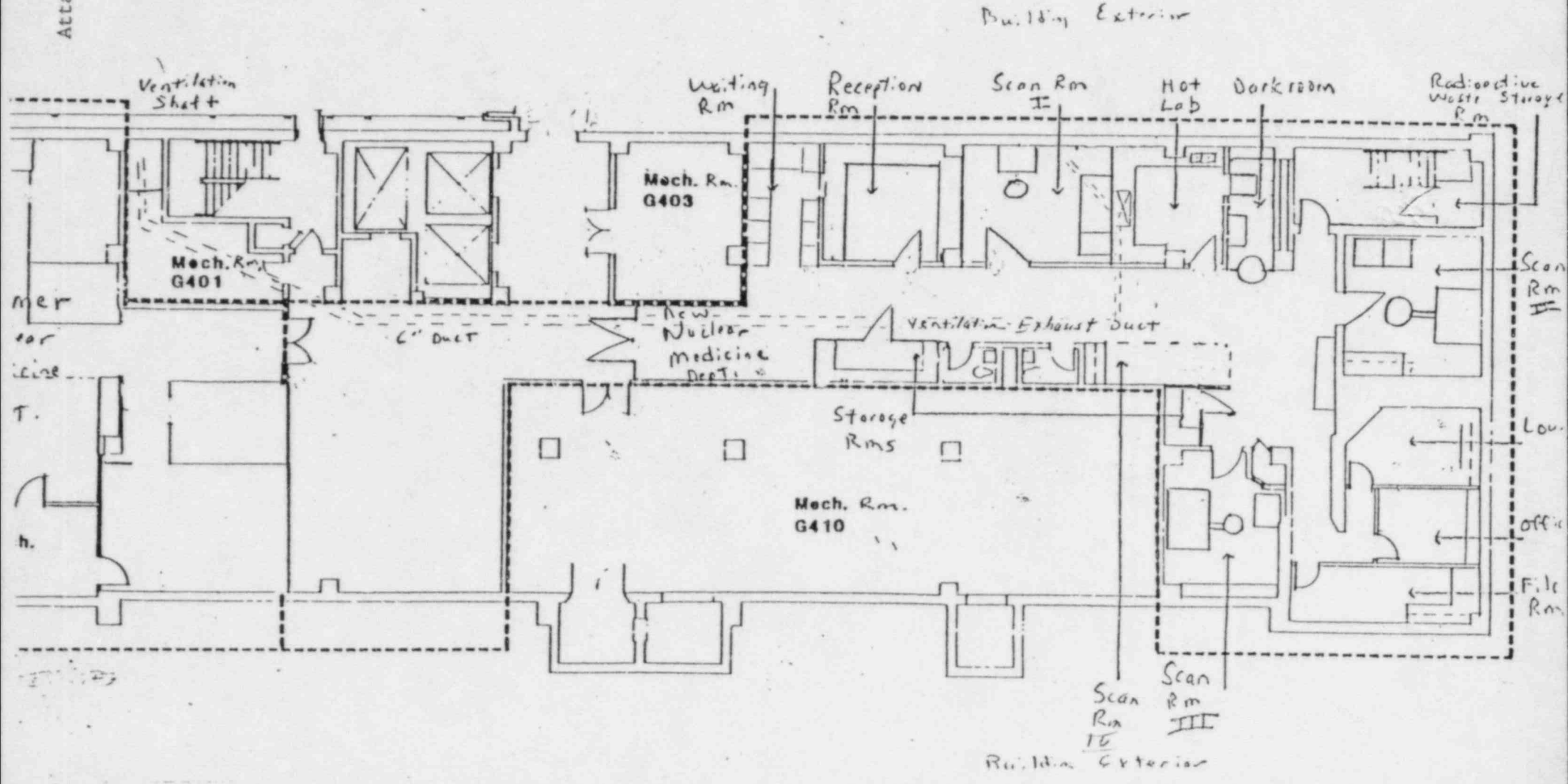
9. Check the shutter for proper operation (User Manual - Standard Scan and QA).

10. Replace the lucite insert (and place the pad on the table). Be sure the lucite insert is placed properly.

11. Monitor radiation levels around the table to insure operator safety.

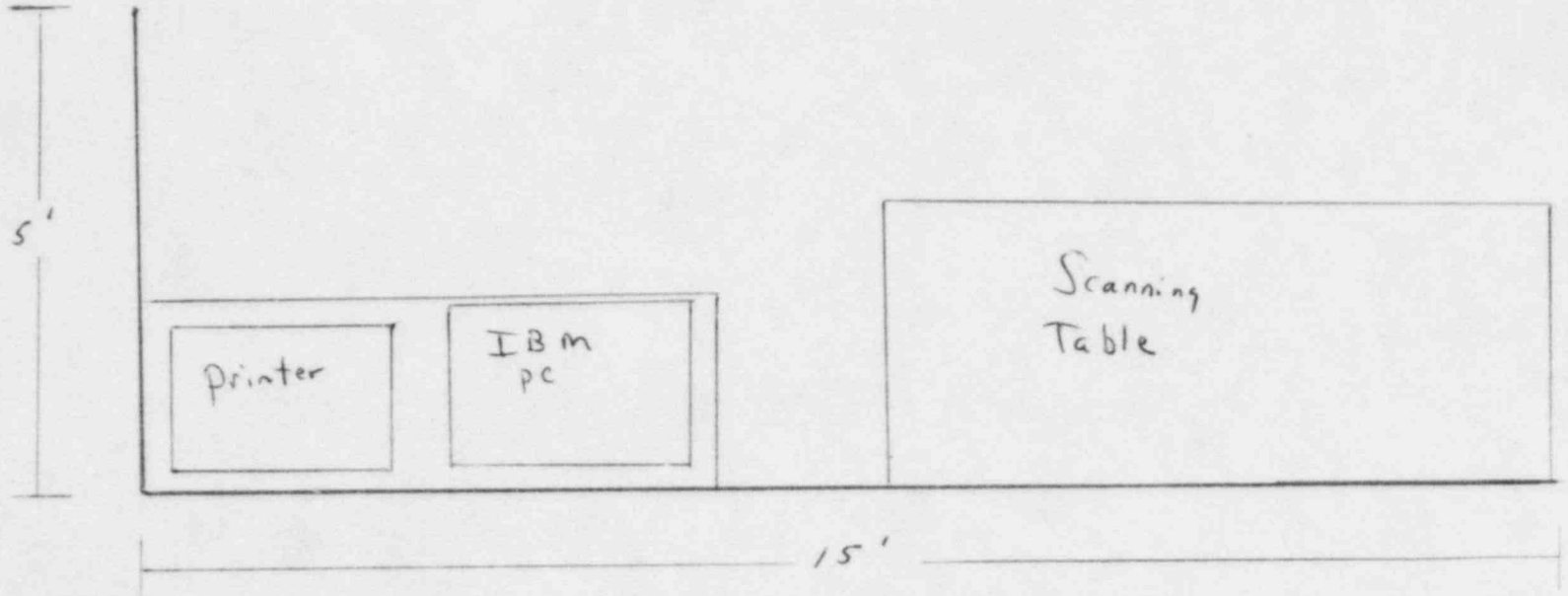
This completes the source installation procedure.

Attachment D



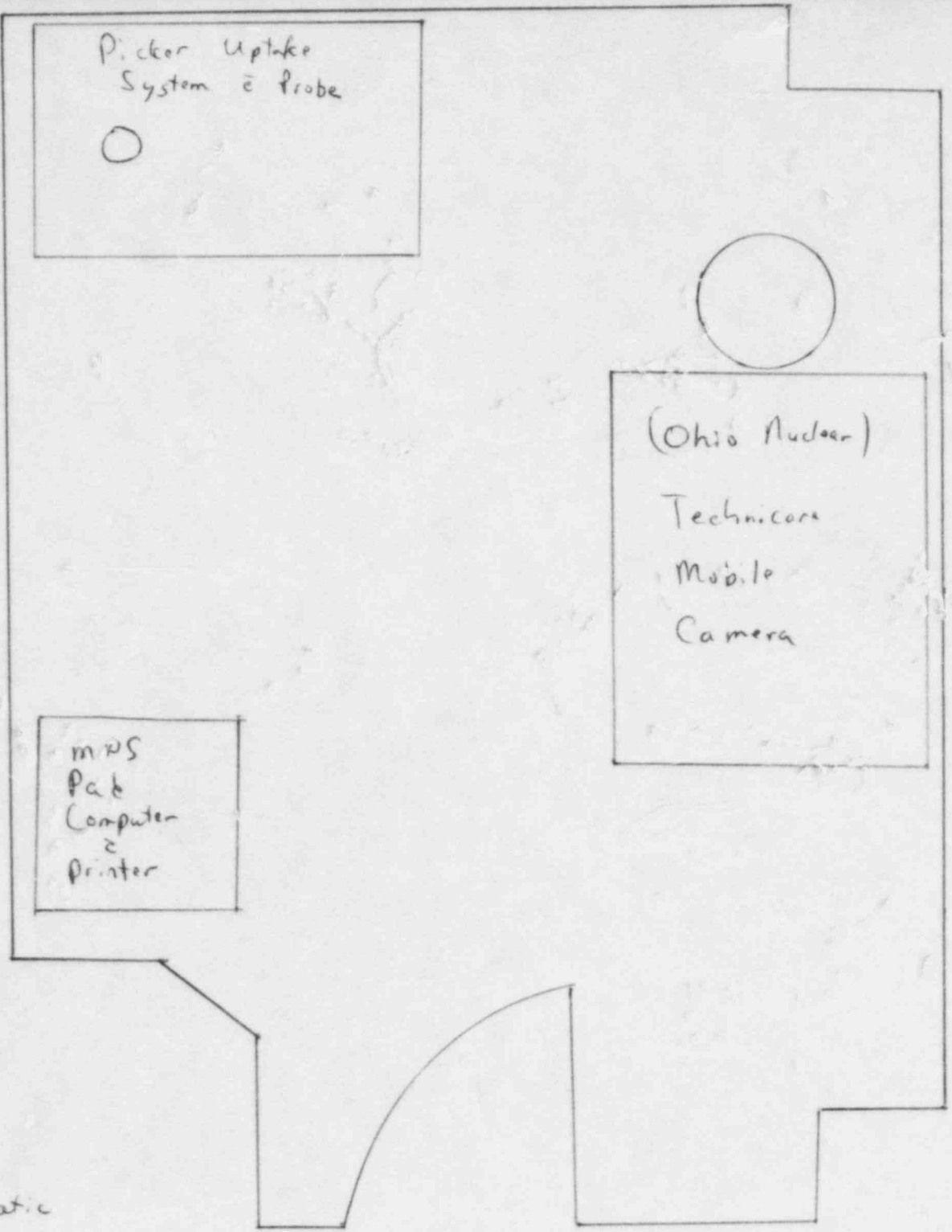
Attachment E

Scan Room IV (formerly Uptake Room)



Scale ½" = 1'

Scan
Room
III



Attachment F

replaces 2-1-84 schematic

Attachment G

CURRICULUM VITAE OF:

MICHEAL E. SANDERS, PhD

DEGREE: Ph.D. in Medical Physics (Biology minor)

PERSONAL DATA:

Current Address: 6930 Carriage Hill Dr. #204, Brecksville, Ohio 44141

Birthdate: 8-1-47 Height: 5'11" Telephone: 216-526-5703
Citizenship: USA Weight: 155 Marital Status: Single

Hobbies and Interests: hiking, backpacking, football, racketball, reading

WORK PREFERENCES:

Type: Clinical Therapy Physics Salary Range: $50,000/yr.
Date Available: December, 1984 Location Preferred: Sun-Belt

OCCUPATIONAL EXPERIENCE:

(1) 1982-Present; Staff Medical Physicist/Project Scientist, Department of Radiation Therapy, Cleveland Clinic Foundation, Cleveland, Ohio; Work Description: Clinical Medical Physics including therapy planning, dosimetry, and calibration using an AECL Therac-20 (photons and electrons), Siemans Mevatron-67, Theratron-780, brachytherapy, and orthovoltage in conjunction with a GE-RTPLAN and an ADAC computor. In charge of medical physics for the joint CCF/NASA cyclotron neutron therapy project involved with the RTOG protocol studies. Instructor to residents and therapy technology students in all physics and treatment planning curricula.

(2) 1978-1982; Graduate Research Assistant, Emory University Clinic, Department of Radiation Therapy, Atlanta, Georgia; Work Description: Clinical Medical Physics involving therapy planning, dosimetry, and calibration of a Varian Clinac-18; Allis-Chalmers 25 MeV betatron, Theratron 80, and a Brown-Boveri 45 MeV betatron in conjunction with a RAD-8 computor. This work work was performed under the supervision of Dr. Patton H. McGinley.

(3) 1978-1982; Graduate Research Assistant, Georgia Institute of Technology, School of Nuclear Engineering and Health Physics, Atlanta, Georgia; Work Description: Developed a REM-responding neutron damage-track dosimeter useable in the neutron energy region between 1 eV and 17 MeV. The dosimeter utilizes CR-39 and polycarbonate polymer foils in conjunction with specially designed ^{6}LiF-Teflon radiator discs to permanantly record neutron-induced damage tracks. The damage tracks are amplified to easily viewable dimensions by sequential chemical and electrochemical etching procedures developed during the course of this work. This DOE sponsored research culminated in my PhD dissertation and was under the direction of Professor Karl Z. Morgan.

(4) 1974-1978; Stockbroker, A.G. Edwards and Sons, Tulsa, Oklahoma

(5) 1967-1974; Junior Physicist, Industrial Nucleonics Corporation, 650 Ackerman Rd., Columbus, Ohio; Work Description: Applied research and development in non-destructive testing/process measurement utilizing beta, gamma, and x-radiation. Optimization of the parameters controlling the source to detector geometry characteristics. Design and development of inert gas ionization detection chambers.

UNIVERSITY INFORMATION: (100% of College Expenses Earned)

	From-To	Degree	(A= 4.0)
(1) Georgia Institute of Technology, Atlanta	1979-82	PhD	GPA: 3.9
(2) Georgia Institute of Technology, Atlanta	1978-79	MANS	GPA: 3.8
(3) Oklahoma State University, Stillwater, Ok.	1977-78	BSET	GPA: 3.6
(4) Ohio State University, Columbus, Ohio	1972-73	Journ.	GPA: 3.5
(5) Oklahoma State University, Stillwater, Ok.	1965-67	ABET	GPA: 3.0

Coursework at Georgia Tech: Medical Physics: 44 hr., Health Physics: 30 hr., Biology: 15 hr., Chemistry 6 hr.

TECHNICAL SOCIETIES:

American Association of Physicists in Medicine, Health Physics Society, American Association for the Advancement of Science, American Nuclear Society

PAPERS AND PUBLICATIONS:

(1) "Thermal Neutron Dosimetry Using Electrochemical Etching", 24th Annual Meeting of Health Physics Society, Philadelphia (1979) Best Paper Award

(2) "Neutron Contamination of High Energy Medical Therapy X-Ray Beams", 46th Meeting of the Southeastern Section of the American Physics Society, Chattanooga, (1979)

(3) "Measurement of Neutron and Heavy Charged Particle Contamination in High Energy Medical Therapy X-Ray Beams Using Recoil Track Registration in Polycarbonate Foils", Proc. 25th Meeting of Health Physics Society, Seattle, (1980)

(4) "Investigation of Contamination Neutrons Generated In and About High Energy Accelerator X-Ray Beams Used in Medical Therapy", Proc. 15th Midyear Meeting of Health Physics Society, Orlando, (1982)

(5) "Design and Application of a Damage Track Neutron Dosimeter Useable in the 1 eV to 17 MeV Neutron Energy Region", Ph.D. Thesis, Georgia Institute of Technology, Atlanta (1982)

(6) "Lung Correction Factors for 45 MV X-Ray Therapy", Medical Physics 9(5), Sept/Oct., 738(1982)

(7) "Photoneutron Contribution From the Thermal Neutron Shield of a Typical Activation Foil Neutron Detector Exposed to a 33 MV X-Ray Beam", accepted for publication in Medical Physics, (1983)

(8) "A REM-Responding Neutron Damage Track Dosimeter Useable in the 1 eV to 17 MeV Energy Region", submitted to Health Physics, (1983)

(9) "Neutron Contamination Measured In and About the Patient Undergoing High Energy X-Ray Therapy", submitted to Medical Physics, (1984)

(10) " Combined Chemical-Electrochemical Etching Technique for CR-39 Polymer Foils in Particle Dosimetry", submitted to Nuclear Tracks, (1984)

REFERENCES:

(1) Antonio Rodriguez-Antunez, MD, Director Department of Radiation Therapy, University Hospitals of Cleveland, 2074 Abington Rd., Cleveland, Ohio Telephone: 216-444-3103

(2) Gwynn Jelden, MD, Staff Therapist, InterCommunity Cancer Center, 5600 Napoleon Avenue, New Orleans, Louisiana Telephone: 504-899-7404/7407

(3) Frank J. Thomas, MD, Interrum Director Department of Radiation Therapy, Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio Telephone: 216-444-5570

(4) Jerrold P. Saxton, MD, Staff Therapist, Department of Radiation Therapy, Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio Telephone: 216-444-5571 Bypass — Very Competent, easy to work with, very dependable Hard worker.

(5) Patton H. McGinley, PhD, Chief Physicist, Division of Radiation Therapy, Emory University Clinic, Atlanta, Georgia Telephone: 404-321-0111 X3539 or X3477

(6) Karl Z. Morgan, PhD, 217 High Cliff Circle, Seven Devils, Bonner Elk, North Carolina Telephone: 704-963-6588

FORM NRC-313M-SUPPLEMENT A (8-78) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Micheal E. Sanders, Ph.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiation Therapy Physics	Eligible	-----

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Oklahoma State 1965-1967, 1977-1978 Georgia Tech 1978-1982	40	25
b. RADIATION PROTECTION	Oklahoma State 1965-1967, 1977-1978 Georgia Tech 1978-1982	30	30
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Oklahoma State 1965-1967, 1977-1978 Georgia Tech 1978-1982	30	10
d. RADIATION BIOLOGY	Same	15	15
e. RADIOPHARMACEUTICAL CHEMISTRY	Same	10	10

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
90 Sr	1000 mCi	Industrial Nucleonics Columbus, Ohio	1967-1973	Industrial
39 Ar	500 mCi	Industrial Nucleonics Columbus, Ohio	1967-1973	Industrial
252 Cf	10 mCi	Georgia Tech	1978-1982	Experimental
137 Cs	500 mCi	Cleveland Clinic Foundation Cleveland, Ohio and Emory University Clinic Atlanta, GA	1978-1985	Medical
^{60}Co	6000 mCi			

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

RECEIVED
SEP 10 1985

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

R. J. Everett, Chief
Material Radiation Protection Section, TPB,
DV&TP, RIV

LICENSEE FEE TRANSMITTAL

A. REGION IV

1. APPLICATION ATTACHED

Applicant/Licensee: Hillcrest Med. Ctr.

Application Dated: July 29, 1985

Control No.: 460735

License No.: 35-09206-03

2. FEE ATTACHED

Amount: $120 / 1,120

Check No.: 003430 / 004327

3. COMMENTS

Signed Laura Hurley

Date August 15, 1985

02120

B. LICENSEE FEE MANAGEMENT BRANCH

3/90

1. Fee Category and Amount: 7C $120 - ck #003430 (ck #004327 returned)

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal _____

License _____

Signed Rita Jacques LFMB

Date 8/29/85